ERNDIM
Quantitative Schemes
Pilot Lipids in Serum

ANNUAL REPORT 2025

Scheme Organiser	Scientific Advisor	Website for reporting results	Administration office
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Published: Rotterdam-Winterswijk, 5th February 2026[1]

1. Purpose

The ERNDIM External Quality Assurance Scheme for Quantitative Pilot Lipids in Serum monitors the analytical performance of laboratories providing screening and diagnosis of patients with inherited metabolic disorders. For details see www.erndim.org / www.ERNDIMQA.nl

2. Participants

56 laboratories ordered 60 sets of samples. 54 sets of data were submitted.

3. Design

The Scheme has been designed, planned and coordinated by the scientific advisors Dr. Susanna Goorden and Dr Marie van Dijk, and Dr. R.M. Schoeman as scheme organiser (on behalf of MCA Laboratory), both appointed by and according to the procedure of the ERNDIM Board.

The design includes samples and reports to provide information with a balance between short-term and long-term reports and between detailed and aggregated information. As a subcontractor of ERNDIM, the MCA Laboratory prepares and distributes the EQA samples to the scheme participants and provides a website for on-line submission of results and access to scheme reports.

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[1] If this Annual Report is not Version 1 for this scheme year, go to 0 for details of the changes made since the last version of this document.

Samples

The scheme works with 4 pairs of lyophilised samples. The compounds included in the scheme are added at 3 levels and at basal level, resulting in 4 concentration levels. Except for 7-DHC and desmosterol, which were alternatively spiked resulting in 2 basal levels for each lipid. All samples are prepared from the same native serum sample. The compounds, their source and the amounts added are listed in Table 1 below. The compounds reported are referred to as analytes. The samples were tested for stability and homogeneity according to ISO 13528, and are stable for the duration of the scheme's submission calendar when stored under defined conditions.

Tabel 1.

Analyte	Source:	Units	Added Amounts			
			Sample Pair 2025. 01 - 06	Sample Pair 2025. 02 - 07	Sample Pair 2025. 03 - 05	Sample Pair 2025. 04 - 08
7-dehydrocholesterol (7-DHC)	Sigma 30800	µmol/L	150.0	10.6	0.0	0.0
7-ketocholesterol (7-KC)	Sigma C2394	µmol/L	0.5	1.5	1.0	0.1
C26:0-lysophospatidylcholine (C26:0-lysoPC)	Sigma 855810P	µmol/L	1.5	0.05	0.0	0.15
Cholestane-3ß. 5α. 6ß-triol	Merck 7000054P	µmol/L	0.8	0.5	0.3	0.1
Cholestanol	Sigma D6128	µmol/L	13.1	92.9	68.1	0.0
Coenzyme Q10	Sigma C9538	µmol/L	4.0	2.0	1.0	0.0
Desmosterol	Merck D6513	µmol/L	0.0	0.0	200.2	10.0
Glucosylsphingosine	Sigma 43659	nmol/L	0.0	100.8	801.2	10.9
Lathosterol	Sigma C3652	µmol/L	0.0	19.8	50.1	99.9
Lyso-globotriaosylceramide (Lyso-Gb3)	Sigma G9534	nmol/L	100.0	49.6	9.6	0.0
Lyso-monosialoganglioside 1 (Lyso-GM1)	Sanbio 24837	nmol/L	57.1	3.6	0.0	14.2
Lyso-monosialoganglioside 2 (Lyso-GM2)	Sanbio 33073	nmol/L	0.0	6.3	1.6	25.4
Lyso-sphingomyelin (Lyso-SM)	Sanbio 100079475	nmol/L	50.1	0.0	20.3	406.1
N-palmitoyl-O-phosphocholineserine (PPCS)	Bioconnect P347920	nmol/L	2003.1	0.0	494.6	49.5
Sitosterol	Merck 567152	µmol/L	199.5	800.4	0.0	20.2

Reports

All data-transfer, the submission of data, and the request and viewing of reports, proceed via the interactive website, www.erndimqa.nl, which can also be reached through the ERNDIM website (www.erndim.org). The results of your laboratory are confidential and only accessible to you (with your name and password). The anonymised mean results of all labs are accessible to all participants. Statistics of the respective reports are explained in the general information section of the website.

An important characteristic of the website is that it supplies short-term and long-term reports.

Short-term reports on the individual specimens are available three weeks after the submission deadline and provide up-to-date information on analytical performance. Although it is technically possible to produce reports immediately, there is a delay of 21 days to enable the scientific advisor to inspect the results and add comments to the report when appropriate.

The **annual long-term report** is based on the design-anchored connection between samples which enables a range of analytical parameters (accuracy, precision, linearity, recovery and inter-lab dispersion) to be reported once the annual cycle has been completed.

The second important feature of the website is the aggregation of results, allowing the participant to choose between detailed reports or an overview of overall performance. "Analyte in Detail" is the most detailed report available as it shows the result of a specific analyte in a sample. "Cycle Review" is a more condensed report summarising the performance of all analytes in a particular sample. Eight such reports are available. The 'Annual Report' is a single report summarising the performance of all eight samples. Depending on the level of detail you require, you can choose to review only the Annual Report or delve into the detailed reports.

4. Discussion of Results in the 2025 Annual Report

In this part, we discuss information that the 2025 annual report provides regarding accuracy, precision, linearity, recovery, inter-laboratory CV and cross-sectional relations. Please keep your annual report at hand when you go through the "guided tour" below. Do remember we only discuss the results of "all labs"; it is up to you to inspect and interpret the results of your own laboratory.

4.1 Accuracy

A first approach to assessing accuracy is to compare your average result over 8 samples with the mean of all laboratories. This is shown in the 'Your lab' and 'All labs' columns under the 'Accuracy' heading. For example, the mean of all laboratories for Cholestanol is 41.6 µmol/litre. You can compare your laboratory's mean to this collective mean.

It is important to recognise that using ERNDIM Quantitative EQA material to establish bias is potentially a limitation. The bias of the method has been determined by comparing results to a derivation of the ERNDIM all laboratory trimmed mean, not a true target value. As the materials produced by the scheme are not reference materials, the bias determined is not a measure of absolute accuracy and is simply a measure of performance relative to other laboratories.

4.2 Precision

Reproducibility is an important quality parameter, and the scheme is designed to assess the intra-laboratory coefficient of variation (CV) as an indicator. The sample pairs can be considered as duplicates and used to calculate intra-laboratory CVs. The precision column shows how your results compare to the mean of all participants. The precision ranges from 6.5% for Glucosylsphingosine to 28.2% for Lyso-GM1. The overall intra-laboratory CV is 15.6%.

4.3 Linearity

Linearity over the relevant analytical range is another important parameter for analytical quality. This is also included in the scheme design. With the weighted quantities on the x-axis and your measured quantities on the y-axis, the coefficient of regression (r) is calculated. In the linearity column you can see how your results compare with the mean of all participants. The mean r ranges from 0.912 for 7-KC to 0.999 for Glucosylsphingosine.

4.4 Recovery

A second way of assessing accuracy is to determine recovery. Recovery is the amount of analyte measured relative to the amount of the same analyte added. This approach assumes that the weighted amount is the target amount. The correlation between the weighted amounts added (on the x-axis) and your measured amounts (on the y-axis) has been calculated. The slope of the correlation curve multiplied by 100% is your recovery. In the Recovery column you can see how your results compare to the average

of all participants. The mean recovery ranges from 35% for Lyso-sphingomyelin to 138% for Lyso-GM1. The overall recovery is 84%.

4.5 Inter-lab CV

A high degree of harmonisation between analytical results from different laboratories is very important for patient care and the use of common reference values. It should be irrelevant in which laboratory the analytical results were obtained. The scheme is also designed to monitor inter-laboratory CV. The column "Data All Labs" shows the number of participants who submitted results per analyte. Most laboratories submitted results for 7-DHC (39), whereas only 7 laboratories measured 7-KC. The inter-laboratory CV ranges from 15.7% for C26:0-lysoPC to 91.4% for Lyso-GM2. The mean inter-laboratory CV for all analytes is 39.3%.

4.6 Cross Sectional Relations

The various parameters discussed above are often interrelated. Often several parameters point to good or poor analytical control. For example, for lyso-Gb3 all parameters indicate relative good performance: precision (CV = 8.9%), linearity (r = 0.996), recovery (94%) and inter-lab variation (inter-lab CV 27.9%) with more than half of laboratories (n=28 datasets) submitting results.

On the other hand, for lyso-GM2 most parameters indicate that good performance is challenging: precision (CV = 24.9%), linearity (r = 0.977), recovery (122 %) and inter-lab variation (inter-lab CV 91.4%) with only a few laboratories (n=10 datasets) submitting results.

4.7 Your performance: Flags

The Annual Report includes flags to help you easily assess your performance. The flags have different colours to indicate poor performance for accuracy, precision, linearity and recovery. Compounds with satisfactory performance in at least 3 out of 4 parameters (no or one flag) are marked with a green flag. Thus, a green flag indicates satisfactory analytical performance. The criteria for flagging can be found in the General Information section of the website.

4.8 Poor Performance Policy

There is a wide variation in the overall performance of individual laboratories. Table 2 shows the percentage of flags scored. 44% of the laboratories have no flags at all and have achieved excellent overall performance. At the other extreme, 2% of the participants scored more than 25% of flags. However, as the 2025 Lipids scheme is in a pilot phase, there is not yet a poor performance policy in place.

Table 2. Percentage flags

% Red flags seen in annual report	Percentage labs in this category	Cumulative percentage of labs
>25%	2%	2%
25%	8%	10%
20 – 25%	4%	14%
15 – 20%	15%	29%
10 – 15%	11%	40%
5 – 10%	12%	52%
0 – 5%	4%	56%
0%	44%	100%

4.9 Certificates
As the Lipids scheme is a pilot no certificate of participation will be provided.

4.10 Additional Specific Remarks of the Scientific Advisor
As some labs experienced issues with separating 7-DHC and desmosterol, in 2025 either one of these compounds was added to the different samples. This led to a better performance. As in 2026 the LIS scheme will no longer run as a pilot the analytes overlapping with the SAS (Special Assays in Serum) scheme will no longer be available in SAS, except for 7-DHC and cholestanol. By doing so, labs which only measure these compounds are not forced to participate in an additional scheme. In addition, this provides the labs that cannot separate 7-DHC and desmosterol the opportunity to still analyze their performance on 7-DHC. Therefore, in the 2026 LIS scheme desmosterol and 7-DHC will no longer be added exclusively.

5. Summary
Overall, the second pilot year of the Lipids scheme ran successfully. The changes mentioned above will be in effect in the 2026 scheme.
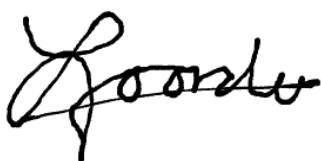
6. Preview 2026 Scheme
The design of the scheme in 2026 will be essentially the same as the 2025, with the addition of cholesterol which is not spiked, but present in the matrix. The scheme will run as a regular scheme starting from 2026.

7. Questions, Suggestions and Complaints
If you have any questions, comments or suggestions, please contact the scientific advisors or the scheme organiser Dr. R.M. Schoeman (mca.office@skbwinterswijk.nl).

Most complaints received by ERNDIM consist of minor misunderstandings or problems with samples, which can usually be resolved via direct contact with the ERNDIM administrative staff. If you wish to file a formal complaint, please email your complaint with details of your issue to admin@erndim.org or contact us through our website at https://www.erndim.org/contact-us/

Rotterdam, 26th January 2026

Dr. S. Goorden
Scientific Advisor

laboratory's performance, unless ERNDIM is required to disclose performance data by a relevant government agency. For details, please see the terms and conditions in the ERNDIM Privacy Policy on www.erndim.org.

Change log (changes since the last version)

Version Number	Published	Amendments
1	5th February 2026	• 2025 annual report published

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